# De effectiviteit van botuline toxine A als injectie in de bekkenbodemspier bij patiënten met chronische bekkenpijn: een dubbel-geblindeerde, gerandomiseerde studie.

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Pelvic floor muscle spasms resulting in chronic pelvic pain may occur as a primary event or secondary to a physical, psychological or pathological factor. First-line treatment consists of pelvic floor physiotherapy. When first-line treatment fails,...

| | |
|---|---|
| **Ethische beoordeling** | Niet van toepassing |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON20966

**Bron**
NTR

**Aandoening**

chronic pelvic pain with pelvic floor hypertonicity

### Ondersteuning

**Primaire sponsor:** Radboudumc, Nijmegen
**Overige ondersteuning:** fund investigator initiated trial, Radboudumc

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

decrease of chronic pelvic pain, measured with a decrease in visual analog scale score (VAS score 0-10) with 33% and the PGI-I of 6 or 7 (better or much better).

# Toelichting onderzoek

### Achtergrond van het onderzoek

Chronic pelvic pain is common, affecting 15% of women aged 18-50. Pelvic floor muscle spasms resulting in chronic pelvic pain may occur as a primary event or secondary to a physical, psychological or pathological factor. First-line treatment consists of pelvic floor physiotherapy. When first-line treatment fails, more invasive interventions can be done. One previously published intervention is injection with botulinum toxin A (BTA) in the pelvic floor muscles. It produces a localized, partial, and reversible chemical denervation of the muscle which results in localized muscle weakness or paralysis. There is some evidence that injection of BTA in the hypertonic pelvic floor muscles decreases pelvic pain in patients with therapy resistant chronic pelvic pain; however this is not investigated in a randomized controlled trial. This is a double-blinded randomized placebo-controlled cross-over trial in which intramuscular BTA will be compared with placebo in patients over 18 years with >6 months of chronic pelvic pain with pelvic floor muscle hypertonicity refractory to first-line pelvic floor physiotherapy, and in which no anatomical cause (such as endometriosis) was found. The main study parameters/endpoints: decrease of chronic pelvic pain, measured by a decrease in visual analog scale score (VAS score 0-10) with 33% and the PGI-I of 6 or 7 (better or much better).

### Doel van het onderzoek

Pelvic floor muscle spasms resulting in chronic pelvic pain may occur as a primary event or secondary to a physical, psychological or pathological factor. First-line treatment consists of pelvic floor physiotherapy. When first-line treatment fails, more invasive interventions can be done. One described intervention is injection with botulinum toxin A (BTA) in the pelvic floor muscles. It produces a localized, partial, and reversible chemical denervation of the muscle which results in localized muscle weakness or paralysis, and possibly pain reduction

### Onderzoeksopzet

baseline t=0, 4, 8, 12, 26 weeks after first injection, and t=30, 34, 38, 52 weeks after secondary injection

### Onderzoeksproduct en/of interventie

The pelvic floor muscles will be injected with either 100 IU BTA or placebo.

# Contactpersonen

## Publiek

WM. Klerkx
Nijmegen
The Netherlands

## Wetenschappelijk

WM. Klerkx
Nijmegen
The Netherlands

# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Female, >18 years

- Chronic pelvic pain according to the ICS with or without dyspareunia

- Vaginal examination with one finger possible

- Pelvic floor hypertonicity measured by physical examination by registered pelvic floor physiotherapist and MAPLe

- Previous physical therapy with registered physical therapist was unsuccessful

- Good understanding of Dutch language

- Willing to provide informed consent

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- (wish for) Pregnancy/lactation during study period

- Previous pelvic floor BTA treatment

- Known hypersensitivity to BTA

- History of neuromuscular or bleeding disorders

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Cross-over |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Dubbelblind |
| Controle: | Placebo |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-07-2017 |
| Aantal proefpersonen: | 92 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Niet van toepassing

| | |
|---|---|
| Soort: | Niet van toepassing |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL6205 |
| NTR-old | NTR6369 |
| Ander register | NL61409.091.17 : ABR |

# Resultaten